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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 05/14/2010

Robert M. Schulman, Esq.
Hunton & Williams
1900 K Street, N.W.
Washington, DC 20006-1109

EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/14/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/628,414

07/29/2003

Paul Barnett

58771.000043

6305

TITLE OF INVENTION: STRATIFIED AND CRYOGENICALLY STORED VACCINES, PROCESS FOR THEIR PREPARATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/16/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

7590

05/14/2010

Robert M. Schulman, Esq.
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Washington, DC 20006-1109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional

NO

\$1510

\$300

\$0

\$1810

08/16/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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HILL, MYRON G

1648

424-184100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/14/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 376 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 376 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/628,414	BARNETT ET AL.	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to papers filed 3/30/10.
2. ☒ The allowed claim(s) is/are 1-48,51 and 55.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09972841.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>3/30/10</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

EXAMINER'S AMENDMENT

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 5/3/2010, Dwight Benner requested an extension of time for 2 MONTH(S) and authorized the Director to charge Deposit Account No. 50-0206 the required fee of \$460 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The restriction requirement is withdrawn and the withdrawn claims are considered and allowed.

Please replace the first line of the specification (the first line as amended in the application transmittal letter and 3/16/07):

--This application is a divisional of U.S. Patent Application Serial No. 09/972,841 filed October 9, 2001, now US 6669947, which claims the benefit under 35 U.S.C. §119 of French application 00/12817 filed October 6, 2000, the disclosure of which is hereby incorporated by reference. --

The following claims were amended:

6. **(Currently Amended)** The composition as defined in Claim[[s]] 1, wherein the antigenic medium is an aqueous or aqueous-alcoholic phase of antigenic material.

7. **(Currently Amended)** The composition as defined in Claim 1, comprising at least one aqueous or aqueous-alcoholic adjuvant phase comprising at least one water-soluble salt of a metal cation and **[[of]]** an organic acid,

wherein said organic acid possesses ~~possessing~~ at least one phosphoric group or one carboxyl group.

9. **(Currently Amended)** The composition as defined in Claim 7, in which the at least one water-soluble salt ~~of a metal cation is~~ comprises a salt of glycerophosphoric, acetic, lactic, tartaric, malic, citric, pyruvic, gluconic, glucuronic, fructoheptonic, gluconoheptonic, glucoheptonic, glutamic, or aspartic acids; or of methionine.

10. **(Currently Amended)** The composition as defined in Claim 9, in which the at least one water-soluble salt ~~of a metal cation is~~ comprises manganese gluconate, calcium gluconate, zinc gluconate, calcium

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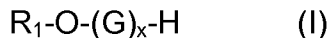
fructoheptonate, calcium glycerophosphate, soluble aluminum acetate or aluminum salicylate.

19. **(Currently Amended)** The composition as defined in Claim 15, wherein the esters of fatty acids comprise acyl radicals ~~comprising~~ containing from 12 to 22 carbon atoms.

20. **(Currently Amended)** The composition as defined in Claim 19, wherein said acyl radicals ~~comprise~~ contain from 16 to 18 carbon atoms.

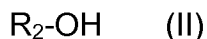
24. **(Currently Amended)** The composition as defined in Claim 1, comprising at least one aqueous or aqueous-alcoholic adjuvant phase comprising:

a) ~~a compound~~ one or more compounds of formula (I):



in which R_1 represents a saturated or unsaturated, linear or branched hydrocarbon radical ~~comprising~~ containing from 1 to 30 carbon atoms, G represents the residue of a saccharide and x represents a decimal number of between 1 and 5 ~~or a mixture of compounds of formula (I), and if desired~~ optionally

b) ~~a compound~~ one or more compounds of formula (II):



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in which R_2 represents, independently of R_1 , a saturated or unsaturated, linear or branched hydrocarbon radical ~~comprising~~ containing from 8 to 30 carbon atoms ~~or a mixture of compounds of formula (II).~~

25. **(Currently Amended)** The composition as defined in Claim 24, for which, in the formula (I), the number x , ~~which represents an average degree of polymerization of the saccharide,~~ is between 1 and 3.

30. **(Currently Amended)** The composition as defined in Claim 24, for which, in the formula (I), the radical R_1 represents a radical ~~comprising~~ containing from 5 to 22 carbon atoms chosen from pentyl, hexyl, heptyl, octyl, nonyl, decyl, undecyl, dodecyl, tridecyl, tetradecyl, pentadecyl, hexadecyl, heptadecyl, octadecyl, nonadecyl, eicosyl, uneicosyl, docosyl, heptadecenyl, eicosenyl, uneicosenyl, docosenyl, heptadecadienyl or decenyl radicals, said radicals being linear or branched.

31. **(Currently Amended)** The composition as defined in Claim 30, for which, in the formula (I), R_1 ~~preferably~~ represents a radical ~~comprising~~ containing from 8 to 20 carbon atoms, said radicals being linear or branched.

32. **(Currently Amended)** The composition as defined in Claim 24, for which, in the formula (II), R_2 represents a radical ~~comprising~~ containing from 8 to 22 carbon atoms chosen from octyl, nonyl, decyl, undecyl, dodecyl,

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tridecyl, tetradecyl, pentadecyl, hexadecyl, heptadecyl, octadecyl, nonadecyl, eicosyl, uneicosyl, docosyl, heptadecenyl, eicosenyl, uneicosenyl, docosenyl, heptadecadienyl or decenyl radicals, said radicals being linear or branched.

35. **(Currently Amended)** The composition as defined in Claim 1, comprising at least one oily adjuvant phase, ~~it being understood that~~ wherein when the antigenic medium comprises a lyophilisate comprising one or more antigens, the composition also comprises either:

at least one aqueous or aqueous-alcoholic adjuvant phase comprising one or more water-soluble salts of metal cations and ~~of~~ organic acids,

wherein said organic acids possess ~~possessing~~ at least one phosphoric group or one carboxyl group~~[[.]]~~; or
a diluent phase for the antigenic medium.

38. **(Currently Amended)** The composition as defined in Claim 37, wherein ~~one of the nonionic surfactants combined with the oil or with the mixture of oil is~~ said nonionic surfactant comprises oleic, ricinoleic or ketostearic acid; or a derivative thereof.

39. **(Currently Amended)** The composition as defined in Claim 38, wherein ~~one of the nonionic surfactants~~ said nonionic surfactant ~~combined with the oil or with the mixture of oil is~~ comprises a mannitol

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oleate or a derivative of mannitol oleate obtained by grafting a hydrophilic functional group.

40. **(Currently Amended)** The composition as defined in Claim 39, wherein said hydrophilic functional group ~~is~~ comprises an amide, amine, alcohol, polyol or ~~[[a]]~~carboxyl functional group; ~~or an~~ ethoxy, propoxy and/or butoxy radical; ~~or~~ a mannitan oleate; or a derivative thereof.

51. **(Currently Amended)** An immunogenic composition comprising the composition as defined in Claim 1 and a frozen carrier suitable for parenteral or intravenous injection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648